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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Greg Marik

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IP Section

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

12/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,961	Applicant(s) MARIK ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-38 and 40-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-38 and 40-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachments 1,2.</u> |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 7, 11, 14-18, 24-26, and 29-39 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38 and 40-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 35 and 45 each recite, "formed of a relatively rigid biocompatible material such that at least the third and fourth surfaces of the center member are not deformed". Support was not found for this limitation in the applicants specification. Support was found for the center member to be a rigid material, an elastomeric material, or a composite material

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composed of an elastomer with hardened surfaces. It is noted however that the embodiment in which applicant is referring to (*at least* the third and fourth surfaces) is the composite embodiment and no support was found for the hardened surfaces to be the rigid biocompatible materials and non-deformable. A hardened surface may be the same elastomer used for the core, simply cross-linked or a lower water content on the surface (not necessarily the “rigid” materials disclosed by applicant, metals, ceramics, etc). Thus the center member having *at least* the third and fourth surfaces of a rigid and non-deformable material is considered new matter. Claims 36-38, 40-44, and 46-54 depend upon claims 35 and 45 and inherit all problems associated with the claims.

Referring to claim 50, applicant has claimed, “the second diameter being less than the first diameter”. Support was not found for this limitation in the specification. Claims 51-54 depend upon claim 50 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35 and 40-49 rejected under 35 U.S.C. 102(e) as being anticipated by Trieu (US 2006/0259144 A1). See figures 22, 23, 25 and respective portions of the specification. Trieu discloses an intervertebral implant comprising a first member (122, 152, 212), second member (124, 154, 214) and center member (126, 156, 216), each member made of rigid materials

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(P0031) and the third and fourth surfaces of the center member being non-deformable (P0003, P0004; P0034). Trieu discloses the members to have the claimed concave/convexities and surface curvatures, see attachment 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trieu (US 2006/0259144 A1). Trieu discloses the intervertebral implant substantially as claimed, however is silent to mention a radius of curvature of the first concave surface. The embodiment shown in figure 25 appears to have a constant radius, however it is unclear. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first concave surface of Trieu to be a constant radius since wherein the general conditions of a claim are disclosed in the prior art (concavity) it is not inventive to discover the optimum or workable ranges (constant radius) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Constant and variable radius articulation surfaces are well known in the art.

Claims 35-38, 40-43 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (US 7,066,958 B2). See figure 28c and respective portions of the specification. Referring to claims 35, 37, 38, 40-43, and 45-48, Ferree discloses an intervertebral implant comprising a first member (upper endplate, fig.28c), second member (lower endplate + piston

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component), and center member (cylinder component + elastomer component). Ferree discloses the members to have the claimed concave/convexities and surface curvatures, see attachment 2. Although the second and fourth surface (piston and cylinder) appear generally flat in the figures, Ferree discloses such piston/cylinder surfaces to be spherical and concave respectively, see col.5 lines 58-60; col.6, line 3. Ferree does not disclose however the peripheral shape of the components (first, second and third peripheries to be circular). Ferree does show other embodiments with several shapes, such as circular, oval, kidney; see figs.7c, 10a, 11a, 20), however does not mention what shape the embodiment of figure 28c has. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have circular peripheries on the member since such would be a simple change in shape, to circular, a shape already shown as useful by Ferree. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Referring to claim 36, Ferree discloses the intervertebral implant substantially as claimed, however is silent to mention a radius of curvature of the first concave surface. The embodiment shown in figure 25 appears to have a constant radius, however it is unclear. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first concave surface of Trieu to be a constant radius since wherein the general conditions of a claim are disclosed in the prior art (concavity) it is not inventive to discover the optimum or workable ranges (constant radius) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Constant and variable radius articulation surfaces are well known in the art.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755.

The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738